

**AMENDMENT TO THE DRAWINGS**

Applicants submit three (3) replacement sheets of drawings for Figures 18-20, which are clearer black and white versions of Figures 18-20.

## **REMARKS**

### **Status of the Claims**

Claims 3-10, 12, and 18-22 are pending in the present application. Claims 1, 2, 11, and 13-17 are canceled without prejudice or disclaimer. Claims 3, 8, and 18-20 are withdrawn as directed to a non-elected invention. Claims 4-7, 9-10, and 12 are amended. Claims 21 and 22 are new. Support for these amendments and new claims is found throughout the specification as originally filed, including, *e.g.*, on page 29, line 15. Applicants reserve the right to claim any canceled subject matter in one or more continuation or divisional applications. Reconsideration is respectfully requested.

Initially, Applicants respectfully request that the newly amended claims and the new claims, which are directed to methods for diagnosing primary esophageal cancer, be considered by the Examiner. The instant claims retain the step of the previously submitted diagnostic kit claims. Specifically, amended claims 4-7, 9-10, and 12 and new claims 21 and 22 include the step of detecting the expression of at least one of the described cancer antigenic polypeptides. Accordingly, the instant claims incorporate subject matter that was previously constructively elected by Applicants. Based upon the foregoing, the instant claims should be properly considered by the Examiner.

### **Color Drawings**

The Examiner objects to the color drawings submitted on September 29, 2006. Specifically, the Examiner states that Applicants are required to submit a petition, an appropriate fee, three sets of color drawings and an amendment to the specification.

Applicants submit that they previously complied with the petition for color drawings and requirements thereof. Applicants respectfully refer the Examiner to the petition, petition fee transmittal, three sets of color drawings, and the amendment to the specification, which was submitted to the Office on September 29, 2006. The petition, fee transmittal and amendment to the specification may be viewed on PAIR. Accordingly, Applicants respectfully request the objection be withdrawn.

**Objection to the Drawings**

The Examiner objects to Figures 18-20. Specifically, the Examiner states that these Figures are not readable. Applicants submit that Figures 18-20, which were submitted to the Office by mail on September 29, 2009, are readable. Notwithstanding the foregoing, in order to expedite prosecution, Applicants are providing substitute electronic copies of Figures 18-20.

**Issues Under 35 U.S.C. § 112, Second Paragraph**

Claims 4-7 and 9-12 are rejected as allegedly indefinite because the phrase “sample derived from a subject” is unclear. Claim 11 is canceled. Accordingly, the rejection is moot in regard to this claim.

In order to expedite prosecution, the claims are amended to cancel the phrase “derived from a subject.” Accordingly, Applicants respectfully request withdrawal of the rejection.

**Issues Under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 1, 4-7, and 9-15 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, *see Office Action*, pages 4-12. Specifically, the Examiner states that the present application supports subject matter directed to a human esophageal cancer polypeptide of SEQ ID NO: 71, and a diagnostic kit for detecting esophageal cancer comprising SEQ ID NO: 71, *see Office Action*, page 4. However, the Examiner asserts that the present application allegedly fails to support claims directed to 1) a human solid cancer polypeptide of SEQ ID NO: 71; 2) a diagnostic kit for detecting solid cancer, breast or gastric cancer; 3) a diagnostic kit for detecting solid cancer in a sample derived from a subject, (as specified in claim 4) or in a sample derived from hemocytes or tissue, (as specified in claim 12), which assertedly encompass metastasized cancer; and 4) a kit comprising a human solid cancer partial polypeptide of SEQ ID NO: 71, as specified in claim 6, *see Office Action*, pages 2, 8, and 9. In addition, the Examiner alleges that the present application fails to support methods for treating or preventing esophageal, breast, or gastric cancer, *see Office Action*, pages 10-11.

Claims 1, 11, and 13-15 are canceled. Accordingly, the rejection is moot in regard to these claims.

Although Applicants do not agree that the specification fails to enable the instant claims, the claims are amended to expedite prosecution. Specifically, the claims are amended to cancel subject matter that the Examiner alleges is not enabled by the present application. In particular, the claims, as amended, do not specify a human solid cancer polypeptide, solid cancer or partial polypeptides. In addition, the amended claims do not specify that the sample is “derived” from a subject, hemocytes, or tissue, but from blood or serum. Applicants submit that a person of skill in the art recognizes that serum is a fraction of blood, and accordingly, the antigenic polypeptide contained in serum must also be contained in blood.

Based upon the foregoing, Applicants submit that claims 4-7, 9, 10, and 12 are enabled by the present application. New claims 21-22 do not specify subject matter that the Examiner alleges is not enabled. Accordingly, Applicants respectfully request the rejection be withdrawn.

**Issues Under 35 U.S.C. § 102(e)**

Claim 1 is rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Publication No. 2008/0014594 to Hestir *et al.*, (“Hestir”). Claim 1 is canceled. Accordingly, the rejection is moot.

Claims 4, 5, 7, and 10-15 are also rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Hestir, *see Office Action*, pages 13-15. Specifically, the Examiner states that Hestir teaches SEQ ID NO: 5, which is 100% identical to SEQ ID NO: 71, *see Office Action*, page 15. The Examiner further states that Hestir teaches an antibody that binds to SEQ ID NO: 71 and methods of diagnosing and treating esophageal, breast, and gastric cancer, *see Office Action*, page 15. In addition, the Examiner states that the claim preambles, which specify diagnostic kits for solid cancers, are viewed as recitations of intended use and are not given patentable weight, *see Office Action*, page 15.

Claims 11 and 13-15 are canceled. Accordingly, the rejection is moot in regard to these claims.

Hestir describes methods for diagnosing cancer by contacting a patient sample with an antibody that binds a disintegrin and metalloproteinase domain 8 precursor protein and detecting the antibody binding. *See, e.g.*, claim 83 in Hestir.

In contrast, independent claims 4 and 5, as amended, are directed to a method for diagnosing primary esophageal cancer comprising detecting the expression of at least one human esophageal cancer antigenic polypeptide in a sample, characterized in that the human esophageal cancer antigenic polypeptide has an amino acid sequence (claim 4) or is encoded by a polynucleotide (claim 5) selected from the described sequences, including SEQ ID NO: 71, (claim 4), or SEQ ID NO: 70, (claim 5). These claims are based upon the finding that a specific antibody, against a known polypeptide, is present in the serum of primary esophageal cancer patients.

In contrast, Hestir fails to teach that the antigenic polypeptide described in SEQ ID NO: 71 or a polynucleotide encoding the antigenic polypeptide, is present in esophageal cancer patients. Further, Hestir does not teach that an antibody against the polypeptide is present in primary esophageal cancer patients. Accordingly, Hestir does not teach a method for diagnosing primary esophageal cancer by detecting the expression of SEQ ID NO: 71 or by an antibody that binds to SEQ ID NO: 71. Based upon the foregoing, Applicants submit that independent claims 4 and 5 are not anticipated by Hestir. Claims 7, 10, 12, and 21 and 22, which incorporate the elements of claim 4, are also not anticipated by Hestir. Accordingly, Applicants respectfully request withdrawal of the rejection.

#### **Issues Under 35 U.S.C. § 103(a)**

Claims 4-7 and 9-12 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Hestir in view of U.S. Patent No. 6,998,241 to Boga, *see Office Action*, pages 16-19. Specifically, the Examiner states that Hestir teaches SEQ ID NO: 71, *see Office Action*, page 18. The Examiner further admits that Hestir fails to teach a kit comprising SEQ ID NO: 71 or a polypeptide encoded by SEQ ID NO: 70, *see Office Action*, page 19. The Examiner also admits that Hestir fails to describe a labeled polypeptide or immobilization of an antibody or a polypeptide on a solid phase, *see Office Action*, page 19. However, the Examiner further alleges that it would have been obvious for a skilled artisan to have combined the teachings in Boga, which describe enzyme immunoassays, with Hestir to arrive at the claimed invention, or to formulate a kit with a polypeptide to detect cancer, *see Office Action*, page 19.

As noted above, Hestir fails to teach or suggest a method for diagnosing primary esophageal cancer by detecting an antigenic polypeptide sequence having the amino acid sequence set forth in SEQ ID NO: 71 or an antigenic polypeptide encoded by the described polynucleotide.

Boga does not remedy the deficiencies of Hestir and is merely cited for describing immunoassays. Accordingly, neither Hestir nor Boga, either alone or in combination teach or suggest all of the elements of amended independent claims 4 and 5, or dependent claims 6, 7, 9, 10, 12, 21 and 22, which incorporate the elements of independent claim 4. Based upon the foregoing, Applicants request the withdrawal of the rejection.

### CONCLUSION

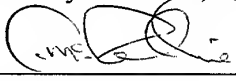
In view of the above Amendment and Remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Linda T. Parker, Reg. No. 46,046, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By  #42874  
Gerald M. Murphy, Jr.  
Registration No.: 28,977  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Attachments: Three (3) Replacement Sheets of Drawings